

AMENDMENTS TO THE SPECIFICATION

Page 2 line 20 to page 3 line 4.

92 The invention improves the durability of elastic polymeric heart valves by eliminating the need to pierce the elastic material of the heart valve during construction of the sewing ring or during implantation. The prosthetic heart valve comprises a stent with an annular base and a plurality of commissures rising from the base. A plurality of apertures or holes ~~apertures~~ circumferentially spaced around the circumference of the base provide access points for a needle to draw a suture through the aperture. Flexible polymeric leaflets are cast or molded over the stent. Polymeric material forming the leaflets covers most of the stent, including at least part of the base. The polymeric material may surround the apertures or holes ~~apertures~~, leaving a central opening in each aperture through which the needle may be inserted without penetrating the polymeric material. Alternatively, only a portion of the base may be covered with polymeric material, such that the polymeric material does not extend to the apertures. In this configuration the needle can pass through an aperture without penetrating the polymeric material. The base may be flared outwardly, forming a frusto-conical ring, to facilitate formation of the central openings in each aperture when the polymeric material is molded over the stent.

Page 3 line 25 to page 4 line 16.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 is a perspective view of a polymer heart valve.

Fig. 2 is a perspective view of a stent for a polymeric heart valve.

Fig. 3 is a perspective view of a portion of a further embodiment of the stent of Fig. 2.

Fig. 4 is a through section of a portion of the stent of Fig. 2, taken at line IV-IV.

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Fig. 5 is a perspective view of the stent of Fig. 2 with elastomeric polymer leaflets molded thereon.

Fig. 6 is a through section of a portion of the stent and leaflets of Fig. 5 taken at line ~~V-V~~
VI-VI.

Fig. 7 is the view of Fig. 6 with a molding pin inserted through an aperture in the stent.

Fig. 8 is a perspective view of a polymeric heart valve with stent and leaflets as shown in Fig. 5 and attached sewing cuff.

Fig. 9 is a partial through section of a portion of a heart valve illustrating attachment of a sewing ring.

Fig. 10 is a through section similar to Fig. 6, illustrating a partially enclosed stent.

Fig. 11 is the view of Fig. 10, further illustrating an attached sewing ring.

Fig. 12 is a view of a portion of a further embodiment of a stent for use in a polymer heart valve.

Fig. 13 is a through section view of the stent of Fig. 12 at line XII-XII, further illustrating an attached sewing ring.

Fig. 14 is a view of a section of a circumferential woven, bias ply band attached to a section of the lower edge of the base of a stent.

Page 7 line 21 to page 8 line 5.

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The embodiment of Fig. 12 and Fig. 13 is similar is to the embodiment of Fig. 10 and Fig. 11 in that it has an aperture in the base 22 of the stent, and at least a portion of the stent is embedded in the polymeric material 46. The embodiment of Fig. 12 and Fig. 13 has a A wire 72 is cast into the base 22 of the stent 16 at an upstream edge 74. In Fig. 12 and Fig. 13 the The entire stent is coated with polymeric material 46 in such a manner as to leave an opening through the aperture 24 and the sewing ring 18 is attached by passing the suture 20 through the apertures 24. The imbedded wire 72 gives additional strength to the base to resist forces acting on the valve in the downstream direction, that is, in the direction of forward blood flow through the valve. Because of this added strength, the apertures 24 can be placed off-center on the base 22. With the apertures closed to the upstream edge 74, more of the material in the base 22 can resist forces acting on the valve in the upstream direction, that is when the valve closes. Consequently, the overall height of the base can be reduced. The apertures may be formed as a plurality of notches 76 along the upstream edge 74 of the base of the stent with the circumferential wire 72 lying along the upstream edge 74 of the base and closing an open side of the notches. The sewing ring 18 can be attached either from the outside, as in Fig. 9, by folding an attachment portion on both the inside and the outside of the base 22, as shown in Fig. 13, or from the inside, as shown in Fig. 8. The base 22 may be canted outwardly to form a frustro-conical ring, as described above in connection with Fig. 2.